PT. Mandiri Inti Buana

Jalan Listrik No. 6
Medan-20112
INDONESIA

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MAY 21 2003

510 (K) SUMMARY

K031020/S1

1.0 Submitter :

Name : PT. Mandiri Inti Buana
Address : Jl. Listrik No.6
Medan – Indonesia, 200112.
Phone No. : +61 4566506
Fax No. : +61 4566806

Date of Summary Prepared :

2.0 Contact Person :

Name : Mr. Ng Poy Sin
Phone No. : +61 4566506
Fax No. : +61 4566806

3.0 Name of the device :

Trade Name 1). Flexiskin, and
2). Multiple or Customers' Trade Name
Device Name : Latex Examination Gloves, Powdered, Non-Sterile
Common Name : Examination Gloves
Classification Name : Patient Examination Gloves (Class I)

4.0 Identification of The Legally Marketed Device :

Class I patient examination gloves, 80LYY, powdered, that meets all the requirements of ASTM standard D 3578 – 01a$^{\varepsilon 2}$ and FDA 1000 ml Water Leak Test.

5.0 Description of The Device :

The Latex Examination Gloves, Powdered, Non Sterile meets all the requirements of ASTM standard D 3578 – 01a$^{\varepsilon 2}$ and FDA 1000 ml Water Leak Test.

6.0 Intended Use of the Device :

The Latex Examination Glove, Powdered, Non Sterile is a disposable device intended for medical purposes that is worn on the examiner's hand to prevent contamination between patient and examiner.

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K03/020/S1

7.0 Summary of The Technological Characteristics of The Device :

The Latex Examination Gloves, Powdered, Non Sterile are summarized with the following technological characteristics compared to ASTM or equivalent standards.

CHARACTERISTICS	STANDARDS	DEVICE PERFORMANCE
Dimensions	D 3578 – 01a^{e2}	Meets
Physical Properties	D 3578 – 01a^{e2}	Meets
Freedom from Pinholes	D 3578 – 01a^{e2} FDA 21 CFR 800.20	Meets
Powder Amount	D 3578 – 01a^{e2} D 6124 – 01	< 10 mg/dm^2/ 39.15 mg/glove
Biocompatability	Primary Skin Irritation in Rabbits	Passes (No primary skin irritation)
	Dermal Sensitization	Passes (No contact sensitizer)

8.0 Substantial Equivalent Based on Assessment of Non-Clinical Performance Data

The performance test data of the non-clinical tests that support a determination of substantial equivalent is the same as mentioned immediately above.

9.0 Substantial Equivalent Based on Assessment of Clinical Performance Data

Clinical data is not needed for gloves or for most devices cleared by the 510(k) process.

10.0 Conclusion

It can be concluded that the Latex Examination Gloves, Powdered, Non Sterile will perform according to the glove performance standards referenced in Section (7) above and meet ASTM standards, and FDA requirements for water leak test on pinhole AQL. Consequently, this device is substantially equivalent to currently marketed devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 21 2003

Mr. Ng Poy Sin
Director
PT. Mandiri Inti Buana
Jl. Listrik No. 6
Medan,
INDONESIA 20112

Re: K031020
Trade/Device Name: Latex Examination Gloves, Powdered, Non Sterile
Regulation Number: 21 CFR 880.6250
Regulation Name: Patient Examination Gloves
Regulatory Class: I
Product Code: LYY
Dated: April 23, 2003
Received: April 28, 2003

Dear Mr. Sin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4618. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Susan Runner, DDS, MA
Interim Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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INDICATIONS FOR USE

Applicant : PT. Mandiri Inti Buana

510(k) Number (if known) : K031020/S1

Device Name : LATEX EXAMINATION GLOVES, POWDERED, NON STERILE

Indications For Use:

Latex Examination Gloves, Powdered, Non-Sterile is a disposable device and made of Natural Rubber Latex intended for medical purposes that is worn on the examiner's hand or finger to prevent contamination between patient and examiner.

_____ _____ _____ _____ _____
Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use _____ OR Over-The-Counter _____
(Per 21 CFR 801.109)

Chin S. Lin

(Division Sign-Off)
Division of Anesthesiology, General Hospital, Infection Control, Dental Devices

510(k) Number: K031020